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FIRM/CO. NAME:	U.S. Patent and Trademark Office
FAX NO:	571-273-0633
FROM:	Ashok K. Janah
DATE:	August 4, 2006
APPLICATION NO:	10/616,448
OUR REFERENCE NO:	NK.103.11.US

TOTAL NUMBER OF PAGES 14 (INCLUDING COVER PAGE)

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BUSINESS PHONE: (415) 538-1555 FACSIMILE NO.: (415) 538-8380

MESSAGE:

Examiner Webman:

Attached please find an Amendment and a Terminal Disclaimer.

Kind regards,

Ashok K. Janah

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Weers et al. Application No: 10/616,448 Confirmation No: 1036 Filed: July 8th, 2003 Title: Phospholipid Based Powers for Inhalation	Group No: 1616 Examiner: WEBMAN, Edward J. Attorney Docket No: NK.103.11 Friday, August 04, 2006 San Francisco, CA 94107

Commissioner for Patents
VIA FACSIMILE: (571) 273-0633

Papers Enclosed

- ☒ Amendment
- ☐ Declaration
- ☐ 0 Drawings
- ☐ Supplemental Information Disclosure Statement
- ☐ PTO-1449 Form
- ☐ Citations
- ☒ Terminal Disclaimer
- ☐ Postcard for Return

Extension of Time

☐ Applicant petitions for an extension of time under 37 C.F.R. 1.136

Extension (Months)	Extension Fee	
	Large Entity	Small Entity
☐ One Month	$120.00	$60.00
☐ Two Months	$450.00	$225.00
☐ Three Months	$1,020.00	$510.00

Total $ 0.00

☐ Applicant believes that no extension of term is required. However, this conditional petition is being made in case applicant has inadvertently overlooked the need for a petition for extension of time.

Fees for Extra Claims

	Claims remaining after amendment	Highest number previously paid for	Number Extra	Rate		Additional Fee
				Large Entity	Small Entity	
Total Claims	23	20	3	$50.00	$25.00	$150.00
Independent Claims	3	3	0	$200.00	$100.00	$0.00
Multiple Dependent Claims			0	$360.00	$180.00	$0.00
Supplemental Information Disclosure Statement						
					Total	**$150.00**

Fee Payment

Terminal Disclaimer Fee	$130.00
Fees for Extra Claims	$150.00
Total	**$280.00**

☐ Attached is check no. _____ in the sum of $0.00.
☒ Please charge Deposit Account No. 10-0258 in the sum of **$280.00**.

CERTIFICATE OF TRANSMISSION (37 C.F.R. § 1.8a):

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or facsimile transmitted to the U.S. Patent and Trademark Office at (571) 273-0633 on the date shown below.

By: Susie Pitzen Date: August 4, 2006
Susie Pitzen

Fee Deficiency

☒ If any additional extension and/or fee is required, please charge Deposit Account No. 10-0258.
and/or
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Please direct telephone calls to: Ashok K. Janah at (415) 538-1555
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Nektar Therapeutics
150 Industrial Road
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Respectfully Submitted,

By: Date: August 4, 2006
Ashok K. Janah
Registration No. 37,487

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Weers et al. Application No: 10/616,448 Confirmation No: 1036 Filed: July 8th, 2003 Title: Phospholipid Based Powders for Inhalation	Group Art Unit: 1616 Examiner: Webman, Edward J. Attorney Docket No: 0103.11 August 4, 2006 San Francisco, California

AMENDMENT AFTER NON-FINAL OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

VIA FACSIMILE
(571) 273-0633

Examiner Webman:

This communication is in response to the Office Action dated May 4, 2006 and is being timely filed within three months of the mailing date of the Office Action.

Certificate of Transmission

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By: _____
Susie Pitzen

Date: August 4, 2006

IN THE SPECIFICATION:

Please substitute the following paragraph for the one on page 8 lines 20 to 31:

Phospholipids from both natural and synthetic sources are compatible with the present invention and may be used in varying concentrations to form the structural matrix. Generally compatible phospholipids comprise those that have a gel to liquid crystal phase transition greater than about 40°C. Preferably the incorporated phospholipids are relatively long chain (i.e. C_{16}-C_{22}) saturated lipids and more preferably comprise saturated phospholipids, most preferably saturated phosphatidylcholines having acyl chain lengths of 16:0 or 18:0 (palmitoyl and stearoyl). Exemplary phospholipids useful in the disclosed stabilized preparations comprise, phosphoglycerides such as dipalmitoylphosphatidylcholine, ~~disteroylphosphatidylcholine~~ distearoylphosphatidylcholine, diarachidoylphosphatidylcholine dibehenoylphosphatidylcholine, diphosphatidyl glycerol, short-chain phosphatidylcholines, long-chain saturated phosphatidylethanolamines, long-chain saturated phosphatidylserines, long-chain saturated phosphatidylglycerols, long-chain saturated phosphatidylinositols.

IN THE CLAIMS:

Please substitute the following listing of claims for the previous claims listing:

1. (Previously presented) A method for the pulmonary administration of a dry powder composition from a passive dry powder inhaler to the respiratory tract of a patient, the method comprising:

providing a dry powder composition comprising particles comprising a lipid matrix and an active agent, and the particles having a particle size of 1-30 microns, mass median aerodynamic diameter of less than 5 microns, and bulk density of less than 0.5 g/cm^3;

loading the dry powder composition into a passive dry powder inhaler having a resistance of from 0.01 to 0.30 $(cmH_20)^{1/2}/Lmin^{-1}$; and

administering the dry powder composition from the inhaler to the respiratory tract of a patient,

wherein the emitted dose is at least 60% for flow rates from 10 to 60 liters per minute.

2. (Cancelled)

3. (Currently amended) A method according to claim ~~2~~ 1 wherein the emitted dose is at least 80% for flow rates from 10 to 60 liters per minute.

4. (Previously presented) A method according to claim 1 wherein the fine particle fraction, which is the fraction of the particles emitted from the inhaler as determined by an Anderson Cascade Impaction or multi-stage liquid impinger, is at least 60%.

5. (Currently amended) A method according to claim 1 wherein the lipid comprises a phospholipid selected from the group consisting of dipalmitoylphosphatidylcholine, ~~disteroylphosphatidylcholine~~ distearoylphosphatidylcholine, diarachidoylphosphatidycholine, dibehenoylphosphatidylcholine, diphosphatidyl glycerol, phosphatidylcholines, saturated phosphatidylethanolamines, saturated phosphatidylserines, saturated phosphatidylglycerols, and saturated phosphatidylinositols.

6-10. (Cancelled).

11. (Previously presented) A method according to claim 1 wherein the lung deposition is greater than 25%.

12. (Original) A method according to claim 1 wherein the lung deposition is greater than 30%.

13. (Original) A method according to claim 1 wherein the lung deposition is greater than 50%.

14. (Currently amended) A method according to claim 1 wherein the active agent is selected from the group consisting of budesonide, tobramycin sulfate, leuprolide acetate, ~~Amphotericin~~ amphotericin B and ~~PTH~~ parathyroid hormone.

15. (Currently amended) A method according to claim 1 wherein the ~~powder comprises~~ particles comprise hollow porous microparticles.

16-20. (Cancelled).

21. (New) A method for the pulmonary administration of a dry powder composition from a passive dry powder inhaler to the respiratory tract of a patient, the method comprising:

providing a dry powder composition comprising particles comprising a lipid matrix and an active agent, and the particles having a particle size of 1-30 microns, mass median aerodynamic diameter of less than 5 microns, and bulk density of less than 0.5 g/cm^3;

loading the dry powder composition into a passive dry powder inhaler having a resistance of from 0.01 to 0.30 $(cmH_20)^{1/2}/Lmin^{-1}$; and

administering the dry powder composition from the inhaler to the respiratory tract of a patient,

wherein the fine particle fraction emitted from the inhaler is at least 60% as determined by an Anderson Cascade Impaction or multi-stage liquid impinger.

22. (New) A method according to claim 21 wherein the emitted dose is at least 60% for flow rates from 10 to 60 liters per minute.

23. (New) A method according to claim 22 wherein the emitted dose is at least 80% for flow rates from 10 to 60 liters per minute.

24. (New) A method according to claim 21 wherein the lipid comprises a phospholipid selected from the group consisting of dipalmitoylphosphatidylcholine, distearoylphosphatidylcholine, diarachidoylphosphatidycholine, dibehenoylphosphatidylcholine, diphosphatidyl glycerol, phosphatidylcholines, saturated phosphatidylethanolamines, saturated phosphatidylserines, saturated phosphatidylglycerols, and saturated phosphatidylinositols.

25. (New) A method according to claim 21 wherein the lung deposition is greater than 25%.

26. (New) A method according to claim 25 wherein the lung deposition is greater than 50%.

27. (New) A method according to claim 21 wherein the active agent is selected from the group consisting of budesonide, tobramycin sulfate, leuprolide acetate amphotericin B and parathyroid hormone.

28. (New) A method according to claim 21 wherein the particles comprise hollow porous microparticles.

29. (New) A method for the pulmonary administration of a dry powder composition from a passive dry powder inhaler to the respiratory tract of a patient, the method comprising:

providing a dry powder composition comprising particles comprising:

(i) a lipid matrix comprising a phospholipid selected from the group consisting of dipalmitoylphosphatidylcholine, distearoylphosphatidylcholine, diarachidoylphosphatidycholine, dibehenoylphosphatidylcholine, diphosphatidyl glycerol, phosphatidylcholines, saturated phosphatidylethanolamines, saturated phosphatidylserines, saturated phosphatidylglycerols, and saturated phosphatidylinositols;

(ii) an active agent comprising tobramycin sulfate;

(iii) a particle size of 1-30 microns;

(iv) a mass median aerodynamic diameter of less than 5 microns; and

(v) a bulk density of less than 0.5 g/cm^3;

loading the dry powder composition into a passive dry powder inhaler having a resistance of from 0.01 to 0.30 $(cmH_20)^{1/2}/Lmin^{-1}$; and

administering the dry powder composition from the inhaler to the respiratory tract of a patient,

wherein the fine particle fraction emitted from the inhaler is at least 60% as determined by an Anderson Cascade Impaction or multi-stage liquid impinger.

30. (New) A method according to claim 29 wherein the emitted dose is at least 60% for flow rates from 10 to 60 liters per minute.

31. (New) A method according to claim 30 wherein the emitted dose is at least 80% for flow rates from 10 to 60 liters per minute.

32. (New) A method according to claim 29 wherein the lung deposition is greater than 25%.

33. (New) A method according to claim 32 wherein the lung deposition is greater than 50%.

34. (New) A method according to claim 29 wherein the particles comprise hollow porous microparticles.

REMARKS

Claims 1, 3-5, and 11-15, and 21-34 are now pending in the application, of which claims 5, 14 and 15 are being amended, and claims 21-34 are being added.

The Examiner reopened prosecution and rejected the claims on grounds that a Terminal Disclaimer signed by the applicant is needed to overcome a non-statutory double patenting rejection made over copending Application No. 10/141,032. Applicant is enclosing a Terminal Disclaimer over Application No. 10/141,032 to address this rejection.

Claim 3 is being amended to correct its dependency.

Claim 5 is being amended to correct the spelling of distearoylphosphatidylcholine. The Specification is also being amended to correspond to the claims.

Claim 15 is being amended for cosmetic reasons to change "powder" to particles.

The Examiner also objected to claim 14 on grounds that the word "Amphotericin" should be changed to "amphotericin" as the initial capital letter suggests a trade name. The Examiner further requested that "PTH" be changed to "parathyroid hormone" for clarity. Claim 14 has been amended in accordance for the Examiner's request and the Specification has been amended to correspond to the same.

The amendments to claim 14 should be entered because they are fully supported by the Specification and add no new matter. The proposed amendments are supported by paragraph 0019 on page 7, which recites: "[e]xamples of active agents useful in this invention include but are not limited to insulin, ... parathyroid hormone (PTH), ... amphotericin B, ..."

Since the proposed amendments only make express a recitation of features that already existed in the original claims, they are not a narrowing of the scope of the properly construed claim. TurboCare v. General Electric Co., 264 F.3d 1111 (Fed. Cir. 2001); Bose Corp. v. JBL, Inc., 274 F.3d 1354 (Fed. Cir. 2001); and Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371 (Fed. Cir. 2001). Thus, the scope of the doctrine of equivalents applied to these claims should not be limited under the rules of Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 2002 Lexis 3818 (May 28, 2002).

Claims 21 to 34 are being added by this Amendment. Independent claim 21 is a modified version of claims 1 and 4. The language "wherein the emitted dose is at least 60% for flow rates from 10 to 60 liters per minute" present in original claim 1 was substituted with the language "wherein the fine particle fraction emitted from the inhaler is at least 60% as determined by an Anderson Cascade Impaction or multi-stage liquid impinger" which is taken from claim 4. The latter language is to the test used to estimate the amount of emitted particles that enters the lung.

Independent claim 29 is a modified version of claims 1 and 4 as described above, and also includes the language of original claim 5 to various phospholipids; as well "tobramycin sulfate" which is taken from original claim 14.

Thus, the added claims 21-34 are fully supported by the Specification and the original claims, and no new matter is being added, and their entry is respectfully requested.

The above-discussed amendments are believed to place the present application in condition for allowance. Should the Examiner have any questions regarding the above remarks, the Office Action is requested to telephone Applicant's representative at the number listed below.

Respectfully submitted,
JANAH & ASSOCIATES, P.C.

Date: August 4th, 2006

By: _____

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Reg. No. 37,487

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